

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8467

Bartle, C.J.

April 27, 2010

Virginia E. Brutto ("Ms. Brutto" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. David A. Brutto, Ms. Brutto's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their
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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In September, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Randall G. Johnson, M.D.⁴ Based on an echocardiogram dated

3. (...continued)

medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Claimant previously submitted a Green Form in June, 2002, based on the same echocardiogram, in which Linda J. Crouse, M.D., F.A.C.C., attested that claimant had moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and an abnormal left atrial dimension. The Show Cause Record does not reflect whether the Trust processed or audited claimant's June, 2002 Green Form. In any event, as claimant does not contest that the only Green Form

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February 2, 2002, Dr. Johnson attested in Part II of Ms. Brutto's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.⁵ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$512,025.⁶

In the report of claimant's echocardiogram, the reviewing cardiologist, Dr. Crouse,⁷ stated that Ms. Brutto had "[m]oderate [mitral] [r]egurgitation," which measured "36.2% of the [left atrial] area." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view

4. (...continued)
at issue is the September, 2004 Green Form, we need not address claimant's earlier Green Form.

5. Dr. Johnson also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

7. In Pretrial Order ("PTO") No. 2640 at 22 (Nov. 14, 2002), we found that 53 claims that had been certified by Dr. Crouse contained diagnoses that were "beyond the bounds of medical reason."

is equal to or greater than 20% of the Left Atrial Area ("LAA").

See Settlement Agreement § I.22.

In September, 2005, the Trust forwarded the claim for review by Rohit J. Parmar, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Parmar concluded that there was no reasonable medical basis for Dr. Johnson's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated only physiologic mitral regurgitation.⁸ In support of this conclusion, Dr. Parmar explained that:

The technician has over estimated the [mitral regurgitant area] by inclusion of low velocity flow which is not representative of [mitral regurgitation]. This is not acceptable. In my opinion the [mitral regurgitation] is trace/physiologic (by using Singh criteria).

Based on the auditing cardiologist's finding of physiologic mitral regurgitation, the Trust issued a post-audit determination denying Ms. Brutto's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁹ In contest,

8. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, physiologic regurgitation is defined as "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or <+ 5% RJA/LAA."

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit (continued...)

claimant argued that under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant also asserted that Dr. Parmar's conclusion that "low velocity flow" should not be included in the measurement of claimant's mitral regurgitation was contrary to the Trust's training instructions presented to auditing cardiologists regarding when mitral regurgitation is considered to be present. In addition, claimant contended that "[q]uantifying the level of regurgitation shown on an echocardiogram is inherently subjective."¹⁰ Finally, claimant suggested that the Trust was not properly applying the reasonable medical basis standard established in the Settlement Agreement and that the auditing cardiologist simply substituted his own opinion for that of the attesting physician.¹¹

The Trust then issued a final post-audit determination again denying Ms. Brutto's claim. Claimant disputed this final

9. (...continued)

Rules contained in PTO No. 2807 apply to Ms. Brutto's claim.

10. In support of this argument, claimant submitted excerpts of depositions of five (5) physicians from other proceedings. None of the testimony submitted by claimant, however, specifically addressed Ms. Brutto's echocardiogram.

11. Claimant also contended that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence that the auditing cardiologist in this claim held any "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not attempted to establish how these filings entitle her to Matrix Benefits, they are not pertinent to the disposition of this show cause claim.

determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Brutto's claim should be paid. On May 11, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6264 (May 11, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on July 24, 2006. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Brutto reasserts the arguments that she made in contest. In addition, claimant contends that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of regurgitation. According to claimant, "[n]either diagnosis is correct or incorrect; both fall within the realm of having a 'reasonable medical basis.'"

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. Moreover, the Trust argues that claimant failed to establish a reasonable medical basis for her claim because Dr. Parmar determined in audit that claimant's attesting physician improperly characterized low velocity flow as mitral regurgitation. The Trust also asserts that, in PTO No. 2640, this court found that characterizing low velocity flow as mitral regurgitation constitutes impermissible conduct. Finally, the Trust contends that "the subjective nature of echocardiography" does not establish a reasonable medical basis that would allow claimant to prevail on her claim.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest Dr. Parmar's finding that claimant had only physiologic mitral regurgitation. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Brutto rests only on Dr. Johnson's check-the-box diagnosis on her Green Form

and the report of her echocardiogram. Mere disagreement with the auditing cardiologist without identification of specific errors by the auditing cardiologist is insufficient to meet a claimant's burden of proof. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. Here, Dr. Parmar determined in audit, and Ms. Brutto does not adequately dispute, that the attesting physician's finding was unreasonable. Specifically, Dr. Parmar noted that "[t]he technician has over estimated the [mitral regurgitant area] by inclusion of low velocity flow which is not representative of [mitral regurgitation]."¹² Contrary to claimant's argument, Dr. Parmar properly applied the reasonable

12. Similarly, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is due to the "subjective nature of echocardiography." Nor has Dr. Parmar merely substituted his opinion for that of the attesting physician. Instead, Dr. Parmar specifically found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Neither claimant nor claimant's attesting physician adequately refuted or responded to this determination.

medical basis standard established under the Settlement Agreement.

Finally, we reject claimant's argument that low velocity flow is considered mitral regurgitation. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation.

See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Parmar concluded that the mitral regurgitant area measured on claimant's echocardiogram included "low velocity flow which is not representative of [mitral regurgitation]." Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.¹³

13. Although claimant asserts that the Trust's training materials define mitral regurgitation as including blue, green or mosaic signals, nothing in these materials reflects or alters this court's previous determination in PTO No. 2640 that improperly characterizing low velocity flow as mitral regurgitation is an unacceptable practice. As claimant did not adequately contest the determination of the auditing cardiologist
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For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Brutto's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

13. (...continued)
that this is precisely what occurred in the review of claimant's echocardiogram, claimant cannot establish a reasonable medical basis for her claim.